

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY**

SANDOZ INC. and RAREGEN, LLC,)	
)	
Plaintiffs,)	
)	Civil Action No. 3:19-cv-10170
v.)	(BRM) (LHG)
)	
UNITED THERAPEUTICS)	ELECTRONICALLY FILED
CORPORATION and SMITHS)	
MEDICAL ASD, INC.,)	CONTAINS INFORMATION
)	DESIGNATED AS HIGHLY
Defendants.)	CONFIDENTIAL
)	

**DEFENDANTS' POST-HEARING BRIEF IN OPPOSITION TO
PLAINTIFFS' MOTION FOR A PRELIMINARY INJUNCTION**

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I. Plaintiffs Have Not Shown Irreparable Harm.

Plaintiffs present no “clear showing of immediate irreparable injury” to their reputations. *ECRI v. McGraw-Hill, Inc.*, 809 F.2d 223, 226 (3d Cir. 1987). There is no evidence—just self-serving speculation—that doctors, insurers, patients, or pharmacies “may believe there is a problem,” *deGoa Aff.* ¶ 39, are “skeptical” of generic treprostinil, Hr’g Tr. (“Tr.”) 7:21, or may “[a]t some point . . . give up on the generic,” *id.* 11:13–15. Plaintiffs can point to no evidence in the record that supports their statements about reputational harm. Even if evidence existed, any reputational harm would be compensable by money. *Instant Air Freight, Co. v. C.F. Air Freight, Inc.*, 882 F.2d 797, 801 (3d Cir. 1989); *Mon Cheri Bridals, LLC v. Bowls*, 2015 WL 1383948, at *5 (D.N.J. 2015). Either failing dooms their motion for an injunction, as do other flaws:

- An injunction would neither cure Plaintiffs’ claimed reputational harm, *Instant Air Freight*, 882 F.2d at 801, which Plaintiffs admit “will persist even if the cartridge restrictions go away,” *deGoa Aff.* ¶ 40, nor restore the 180-day exclusivity period that they admit “has expired,” Tr. 15:8–9.
- If there were harm, it would not be “immediate,” *Acierno v. New Castle Cty.*, 40 F.3d 645, 654 (3d Cir. 1994), because it would have occurred nine months ago when Plaintiffs chose to launch to reap short-term gains, Ex. 813, with full knowledge of the effects they now claim as damages, *e.g.*, Ex. 512.

- Plaintiffs’ self-inflicted harms cannot support an injunction. *Ride the Ducks of Phila., LLC v. Duck Boat Tours, Inc.*, 138 F. App’x 431, 434 (3d Cir. 2005); *Mylan Inc. v. SmithKline Beecham Corp.*, 2010 WL 4181139, at *4 (D.N.J. 2010).

II. Plaintiffs’ Antitrust Claims Are Meritless.

A. Plaintiffs Cannot Deny the Existence of Reasonable Alternatives.

The evidence is un rebutted that Plaintiffs failed to avail themselves of “reasonably available alternatives,” and were not foreclosed from any market or deprived of an opportunity to compete. *Eisai, Inc. v. Sanofi Aventis U.S., LLC*, 821 F.3d 394, 406 (3d Cir. 2016); *Omega Env’tl, Inc. v. Gilbarco, Inc.*, 127 F.3d 1157, 1163 (9th Cir. 1997). Sandoz knew it needed cartridges since 2011, Ex. 1068, given “how important the cartridges are” to subcutaneous delivery. Tr. 18:8–9. Sandoz learned in 2016 that the CADD-MS 3 was discontinued, Ex. 5, a “publicly known” fact. Jeffs Dep. 102:12–23, 261:25. Contrary to Plaintiffs’ misstatement that Smiths’ 2015 end-of-life notice “did not relate to cartridges,” Tr. 48:1–2, that notice in fact announced that cartridges would be discontinued as early as 2018. Ex. 1082, at 5. In 2017, Sandoz tried but could not find just *two* cartridges for testing. Ex. 20. An “equally efficient competitor” who learns a needed device is discontinued must help itself—approach a manufacturer, invest “a significant amount of time and resources,” *Eisai*, 821 F.3d at 406, and pursue an “existing or potential alternative” solution, *Omega*, 127 F.3d at 1163. Plaintiffs did nothing.

Plaintiffs could have secured a cartridge or pump prior to launch that swiftly would have paid for itself. In fact, Plaintiffs prototyped a cartridge within months for less than \$50,000, deGoa Aff. ¶¶ 26–31, discussed how to “prevent our cartridge from being used with other generics,” Ex. 126, and were on track for launch in the fall of 2019, Ex. 372. Remarkably, Plaintiffs rejected a licensing offer from Smiths in January 2019 that would have accelerated the work, Ex. 1085. Plaintiffs also could have cleared a pump used for Remodulin overseas within months, Ex. 1104, Talpade Rpt. ¶¶ 96–98 & Tbl. 1, or customized an insulin pump for \$1.5 to \$3.5 million, which Smiths did in one year to develop the CADD-MS 3. Collins Dep. 29:5–36:22, Talpade Rpt. ¶¶ 84–92. Such costs would be dwarfed by up to [REDACTED] in expected revenue within a single year. Ex. 813.

Plaintiffs’ defenses of their inaction do not hold water:

- Plaintiffs argue that they did not have to pursue alternative devices because it was impossible for them to “figure out what was going on” and “then remedy it,” Tr. 53:10–11, but this claim is belied by the unrebutted evidence cited above.
- Plaintiffs claim they were misled by the ANDA agreement, but that contract disclaimed “any right to any Third Party . . . delivery device,” Ex. 1006, not just “UTC-developed delivery devices” as Plaintiffs falsely represented. Tr. 50:24–25.
- Plaintiffs claim they were lulled by Accredo, whom they “trust[ed]” to provide devices, Toms Dep. 92:5, but they never sought specific assurances, much

less a purchase order or contract, that Accredo could or would supply devices for subcutaneous treprostinil. The two emails Plaintiffs cite do not even reference subcutaneous delivery, nor do they mention cartridges or any supply commitment. A 2017 notation that Accredo would provide “pump & other kit accessories,” Ex. 906, cannot have provided the comfort Plaintiffs now claim: Sandoz suspended investment in the product *after* that email because of “issues with pump,” Ex. 824, Ex. 1065, Ex. 379. Confronted with their self-inflicted lack of a device, Ex. 1069, Sandoz employees confessed their lack of diligence. Ex. 605, Ex. 606, Ex. 607.

Yet Plaintiffs ask the Court to upend the status quo and force UTC to give them the cartridges it secured by foresight, investment, and risk assumption.

B. Defendants’ Agreements Are Procompetitive.

No cartridges would have existed after 2018 without UTC’s funding, Stamp Decl. ¶ 25, because Smiths stopped making them for business reasons, *id.* ¶ 7, Quinn Decl. ¶¶ 6–9, 15. Defendants’ agreements added output, deterred free-riding, and ensured supply. *Ohio v. Am. Express Co.*, 138 S. Ct. 2274, 2289 (2018); *Race Tires Am., Inc. v. Hoosier Racing Tire Corp.*, 614 F.3d 57, 76 (3d Cir. 2010). Plaintiffs do not rebut these facts.

UTC made “‘possible the very activity that is allegedly restrained’” by funding the manufacture of devices Smiths otherwise would have stopped making. *Gemini Concerts, Inc. v. Triple-A Baseball Club Assocs.*, 664 F. Supp. 24, 27 (D.

Me. 1987). Unable to contest that fact, Plaintiffs argue that cartridges were created without exclusivity in mind, and that Defendants only restricted access to cartridges in 2019, when Plaintiffs hoped to launch. That is refuted by the 2016 agreement’s purpose to “[r]estrict sales of 3ml cartridge to US/CAN Remodulin patients to extend supply,” Ex. 264, and its text, which restricted pumps *and* cartridges (“Product”) “to ensure supply is available for use in connection with Remodulin,” and granted UTC a right of first refusal that would be meaningless otherwise. Ex. 67. The parties knew at the time that the effect was cartridge “exclusivity,” Ex. 69, with a “Remodulin-only” restriction, Ex. 462. Later amendments and agreements “stem from this original agreement” and its “restrictive covenants,” Rao Dep. 32:14–25, and Smiths agreed to secure pharmacy contracts to restrict cartridges to Remodulin patients. Ex. 202, Rhodes Decl. ¶ 11.

When UTC learned in 2018 that contracts were not in place, it stepped up its monitoring of cartridge allocation, agreed to take responsibility for cartridges and contract directly with the pharmacies, and approved every request it received, *id.* ¶¶ 17–23, Gray Decl. ¶¶ 7–8, so *no patient missed a single dose of medicine*. Tr. 20:19–20. Plaintiffs cannot “isolate” those acts from the rest of the transaction, *Meijer v. Barr Pharm.*, 572 F. Supp. 2d 38, 49 (D.C. Cir. 2008), assess only “the aftermath,” *Polk Bros., Inc. v. Forest City Enters., Inc.*, 776 F.2d 185, 189 (7th Cir. 1985), and disregard Defendants’ “conduct, as a whole,” *Eisai*, 821 F.3d at 407.

Respectfully submitted,

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